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TITLE: Establishment of Peripheral Nerve Injury Data Repository to Monitor and Support Population Health Decisions

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| 13. SUPPLEMENTARY NOTES | | | |
| 14. ABSTRACT The current award is to carry out an Ambispective (prospective and retrospective) epidemiologic chart reviews of patients who were referred to San Antonio Military Medical Center (SAMMC) and Walter Reed National Military Medical Center (WRNMMC) for Peripheral Nerve Injury (PNI) treatment. A database, the Peripheral Nerve Injury Database (PNIDB), will be established to catalog and describe the characteristics, mechanisms, management, and outcomes of PNIs using both retrospective chart review and prospective patient enrollment. Collected data will be utilized to 1) describe the outcomes of various PNI and 2) suggest outcomes that support population health decisions for patients with PNIs. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life. Follow-up data collection will accurately document PNI recovery outcomes. This prospective data will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions. Data collected will include combat related and non-combat related PNIs to fully characterize all forms of PNI. | | | |
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1. INTRODUCTION:

The purpose of this study is to catalog and describe the characteristics, mechanisms, management, and outcomes of PNIs using both retrospective chart review and prospective patient enrollment. Collected data will be utilized to 1) describe the outcomes of various PNI and 2) suggest outcomes that support population health decisions for patients with PNIs. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life. Follow-up data collection will accurately document PNI recovery outcomes. This prospective data will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions.

KEYWORDS: Peripheral Nerve Injury, Database, Data Repository, Nerve

2. OVERALL PROJECT SUMMARY:

Due to the delays with WRNMMC IRB it was decided by the PI to have SAMMC become the lead site for this project. A Clinical Research Manager and a Clinical Research Assistant were hired at SAMMC to complete the regulatory submissions. With the addition of the additional team members at SAMMC Major Task 1 has been substantially completed. The team has submitted all documentation to HRPO and we are awaiting final approval which is anticipated in July of this year. A new updated SOW has been created (V8 06-12-17) to reflect clarifications to Major Tasks 4 & 5.

Major Task 2 is currently being worked on with the help of a database manager at SAMMC. All software has been installed (sub-task 2.1) The PNIDB team anticipates completion of sub-tasks 2.2 through 2.5 by the end of month 13. Major Task 3 will begin immediately after sub task 2.5 has been completed, Sub Task 3.1-3.3 (Data entry and validation) will begin month 14. It is still anticipated that all interventions will be completed before the end of year 2. Follow-up of the research subjects may require a No Cost Extension (NCE) as disclosed in the submitted quarterly reports.

3. KEY RESEARCH ACCOMPLISHMENTS

We have received IRB approval, with IRB of record being SAMMC IRB, on 16 May 2017. HRPO full submission was submitted to MRMC on 30 May 2017.

4. CONCLUSION:

Progress has been considered satisfactory with the decision to make SAMMC the lead site. Receiving full IRB approval was a significant milestone given all the regulatory obstacles faced at WRNMMC in year 1. HRPO submission has completed and we anticipate having HRPO approval in July and to start enrollment.

5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Publications: Noting to report

Abstracts: Nothing to report

Presentations: Nothing to report

6. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

7. REPORTABLE OUTCOMES

Nothing to report

8. OTHER ACHIEVEMENTS:

Nothing to report

9. REFERENCES:

SUR-90-4220 References

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10. APPENDICES:

None

11. TRAINING OR FELLOWSHIP AWARDS:

None

12. COLLABORATIVE AWARDS:

No collaborative awards were executed

13. UPDATED QUAD CHART & SOW: See attached